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2020 K Street, NW
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EXAMINER

STIGELL, THEODORE J

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte KARLA WEAVER and PAUL DICARLO

Appeal 2010-002116
Application 10/768,571
Technology Center 3700

Before: JOHN C. KERINS, WILLIAM V. SAINDON, and
MICHAEL C. ASTORINO, *Administrative Patent Judges*.

SAINDON, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Appellants appeal under 35 U.S.C. § 134 from the Examiner's decision rejecting claims 1-10, 12-14, 16-18, 20, and 21. Claims 11, 15, and 19 are canceled. We have jurisdiction under 35 U.S.C. § 6(b).

The Claimed Subject Matter

Claim 1, reproduced below, is illustrative of the claimed subject matter.

1. A pressure activated valve comprising:
 - a valve housing defining a lumen for receiving bodily fluids therein;
 - a flexible membrane disposed in the valve housing, the flexible membrane including a slit extending therethrough so that the flexible membrane may be moved between an open and a closed configuration based on fluid pressure within the lumen; and
 - a first nonthrombogenic coating formed on fluid contacting surfaces of the flexible membrane, wherein the nonthrombogenic coating includes hydrogel.

References

The Examiner relies upon the following prior art references:

Merrill	US 3,673,612	Jul. 4, 1972
Frisch	US 4,447,237	May 8, 1984
Steigerwald	US 5,009,391	Apr. 23, 1991

Rejections¹

- I. Claims 1-7, 10, 12-14, 16, and 17 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Frisch and Merrill.

¹ The Examiner withdrew the rejections based on Weaver and Moorehead because of those references' disqualification as prior art under 35 U.S.C. § 103(c). Ans. 11-12.

- II. Claims 8, 9, 18, 20, and 21 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Frisch, Merrill, and Steigerwald.
- III. Claims 18, 20, and 21 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Steigerwald and Merrill.

SUMMARY OF DECISION

We AFFIRM.

OPINION

A. The Frisch / Merrill Combination

The Examiner rejected independent claim 1 as unpatentable over a proposed combination of the valve of Frisch and the nonthrombogenic coating of Merrill. Ans. 3-5. The Examiner found that the slit (23) of the flexible membrane of Frisch is capable of being “moved between an open and a closed configuration based on fluid pressure within the lumen.” Ans. 4. The Examiner also found that Frisch teaches a nonthrombogenic coating, but not explicitly that the coating includes a hydrogel. *Id.* The Examiner concluded that it would have been obvious to include the nonthrombogenic coating of Merrill, which includes a hydrogel, to the valve of Frisch. Ans. 5.

Appellants separately argue independent claims 1, 10, and 14, but only present particular arguments with respect to the limitations of claim 1. Accordingly, we select claim 1 as representative of claims 1-7, 10, 12-14, 16, and 17. Appellants raise two issues with respect to the Examiner’s proposed combination of Frisch and Merrill:

- 1) Does the valve of Frisch satisfy the requirement of claim 1 that “the flexible membrane may be moved between an open and a

closed configuration based on fluid pressure within the lumen”?

Br. 5-6.

- 2) Did the Examiner properly conclude that the teachings of Frisch and Merrill render obvious a valve having a nonthrombogenic coating including hydrogel as required by claim 1? Br. 7-8.

1) The Flexible Membrane

It is well established that claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. *See, e.g., In re Schreiber*, 128 F.3d 1473, 1477-78 (Fed. Cir. 1997). In order to satisfy the functional limitations in an apparatus claim, the prior art apparatus must be capable of performing the claimed function. *Id.* at 1478. In this case, the Examiner found that slit 23 of Frisch functions as required by claim 1. Ans. 4. In particular, the Examiner found that the device of Frisch is “specifically designed to resist opening when used in the disclosed applications,” and that “there are ... fluid pressures that would open the valve in the presence of such a pressure and close the valve in the absence of such a pressure. Such pressures would not necessarily destroy the device.” Ans. 9.

The Examiner’s findings are consistent with the disclosure of Frisch. The slit 23 (a flexible membrane) is held closed by pressurized chamber 12. Frisch, col. 7, ll. 32-41. Frisch describes the slit as able to withstand the fluid pressures of the shunt path 3 up to a certain pressure. *Id.* at ll. 17-26. Accordingly, we find that Frisch describes the slit to be capable of remaining closed up to a certain fluid pressure, after which the slit would necessarily open.

Appellants argue that the opening of the slit “represents a failure of the device of Frisch.” Br. 6. However, this so-called “failure” is a failure to

withstand the fluid pressures as designed, not the device physically being damaged or destroyed. That is, given the arrangement of the slit and the pressurized chamber 12 holding the slit closed, a fluid forcing open the slit would not destroy the slit, but merely allow the fluid to flow out of the slit. While this may not be considered a desirable opening in some contexts, the structure of Frisch is clearly capable of opening and closing based upon a fluid pressure. Claim 1 does not limit the membrane to open or close based on certain events occurring or based on certain pressures, only that it opens or closes based on fluid pressure. Accordingly, the Examiner's finding that Frisch satisfies the functional limitation at issue is supported by a preponderance of the evidence. *See In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992) ("After evidence or argument is submitted by the applicant in response, patentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument").

2) The Nonthrombogenic Coating

Appellants argue that "Merrill discloses formation of a material which is adapted to include an anticoagulant rather than a coating for use on existing surfaces." Br. 7. Claim 1 does not require the coating to be placed on existing surfaces, however, but rather the coating is merely "formed on fluid contacting surfaces of the flexible membrane." As the Examiner found, Merrill discusses using the nonthrombogenic heparin-bonded hydrogels as "readily formed into a wide variety of shapes such as membranes, tubes, rods, [and] valves." Col. 4, ll. 29-31; *see also* claims 7 (a "process for making a non-thrombogenic polymer surface or membrane") and 8 ("wherein the polymer is a hydrogel and the anticoagulant is heparin"). The Examiner found that such a material would be recognized as

useful by one of ordinary skill in the art as a coating (membrane) in the valve of Frisch. Ans. 10. The Examiner concluded that such a combination would allow for “more uniform distribution of heparin and lower costs.” Ans. 5; Merrill, col. 6, ll. 24-33. Accordingly, the Examiner’s proposed combination appears to be nothing more than incorporating a known material (the membrane in Merrill) into a device (the valve of Frisch) to take advantage of the material’s known properties (low thrombogenicity) with predictable results (uniform distribution, lower cost). *See In re Leshin*, 277 F.2d 197, 199 (CCPA 1960) (the selection of a known material based upon its suitability for the intended use is a design consideration within the skill of the art). Appellants do not raise any compelling arguments as to why the Examiner’s conclusion of obviousness is in error.

As such, we sustain the rejection of claim 1; claims 2-7, 10, 12-14, 16, and 17 fall with claim 1. Appellants argue that the Examiner’s rejection of claims 8, 9, 18, 20, and 21 (Rejection II) is in error for the unpersuasive reasons presented with respect to claim 1 above. Br. 9-10. Consequently, we sustain the Examiner’s rejection of claims 8, 9, 18, 20, and 21 (Rejection II) for the reasons set forth above with respect to claim 1.

B. The Steigerwald / Merrill Combination

The Examiner also rejects independent claim 18 in view of a proposed combination of the teachings of Steigerwald and Merrill (Rejection III). Ans. 5-7. Claim 18, like claim 1, requires a flexible membrane having a slit and being able to move between an open and closed configuration based on fluid pressure in the lumen. The Examiner found that the flexible membranes (76 and 82 or 90 and 94) of Steigerwald are movable between an open and closed configuration based on fluid pressure in the lumen. Ans. 5-

6. Appellants raise the issue of whether Steigerwald describes or suggests a flexible membrane openable based on fluid pressure within the lumen. Br. 11.

The Examiner does not point to any teachings in Steigerwald regarding a pressure at which the flexible membranes 76, 82, 90, or 94 open or close in response to fluid pressure. In Steigerwald, a catheter 56 is passed through valve members 76 and 82 of the valve assembly 20; the valve members prevent the escaping of blood when the catheter has been inserted and “further assure that no air or blood will pass through the first and second valve members **76** and **82** when the catheter **56** is removed from the valve assembly **20**.” Col. 4, ll. 23-51. We do not find any discussion in Steigerwald regarding a fluid pressure at which air or blood would pass through the valve members, and, in fact, Steigerwald appears to suggest that there may not be any such pressure. Col. 4, ll. 47-51 (“**no** air or blood will pass through”) (emphasis added). In addition, we find that the valves in Steigerwald function in a different manner (with flaps that straighten to close) than the valves in Frisch (with a compressive member). *Compare* Steigerwald, fig. 6, items 90, 94 *with* Frisch, fig. 2, item 12. Accordingly, we find that the Examiner’s finding that the flexible membranes 76, 82, 90, or 94 open or close in response to fluid pressure is not supported by a preponderance of the evidence. *Oetiker*, 977 F.2d at 1445. Therefore, the Examiner’s rejection of claims 18, 20, and 21 (Rejection III), which relies on this unsupported finding, is in error.

DECISION

A. We affirm the Examiner’s decision rejecting claims 1-7, 10, 12-14, 16, and 17 as unpatentable over Frisch and Merrill (Rejection I) and claims

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8, 9, 18, 20, and 21 as unpatentable over Frisch, Merrill, and Steigerwald
(Rejection II).

B. We reverse the Examiner's decision rejecting claims 18, 20, and 21 as
unpatentable over Steigerwald and Merrill (Rejection III).

No time period for taking any subsequent action in connection with
this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED

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